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Attorney Docket No.:

PENN-0788

Inventors:

Schlaepfer et al.

Serial No.:

10/082,032

Filing Date:

February 21, 2002

Examiner:

Not Yet Assigned

Group Art Unit:

1632

Title:

Compositions and Methods for Inhibiting Motor Neuron Degeneration

I, Jane Massey Licata, Registration No. 32,257, certify that this correspondence is being depositing with the U.S. Postal Service as First Class mail in an envelope addressed to the U.S. Patent and Trademark Office, Box 2327, Arlington, VA 22202

On this date: July 12, 2002

Jane Massey Licata, Registration No. 32,257

U.S. Patent and Trademark Office Box 2327 Arlington, VA 22202

Sir:

## INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. \$1.56 and in accordance with 37 C.F.R. \$\$1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. \$1.56(b).

(XXX) In accordance with \$1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in \$1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- ( ) In accordance with \$1.97(c), this Information Disclosure Statement is being filed after the period set forth in \$1.97(b) above but before the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311, therefore:
  - ( ) Certification in Accordance with \$1.97(e) is set forth below; or
  - ( ) The fee of \$180.00 as set forth in \$1.17(p) is attached.
- ( ) In accordance with \$1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with \$1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in \$1.17(T)(T)(T).
- ( ) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.
- (XXX) In accordance with \$1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously

submitted to the U.S. Patent and Trademark Office in prior application Serial No. 09/994.420, filed November 27, 2001, or application Serial No. 09/489.979, filed January 21, 2000 for which a claim for priority under 35 U.S.C. \$120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- ( ) The relevance of the listed references in a foreign language is as stated in the specification at pages @@.
- (XX) All listed references are in the English language.

Respectfully submitted,

Janinossfeedi

Jane Massey Licata Registration No. 32,257

Date: July 12, 2002

Licata & Tyrrell P.C. 66 E. Main Street Marlton, New Jersey 08053

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Form PTO-1449 Modified	Docket No. PENN-0788	Serial No. 10/082,032	H CEN	品
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)	Applicant Schlaepfer et al.		ER 160	Ä
U.S. Department of Commerce	Filing Date February 21, 2001	Group <b>1632</b>	0/2900	Ë
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AA	Bruijn, L.I. and Cleveland, D.W., "Mechanisms of selective motor neuron death in ALS: insights from transgenic mouse models of motor neuron disease", Neuropathol. Appl. Neurobiol., 1996,22:373-387	
	АВ	Camete-Soler et al., "Mutation in Neurofilament Transgene Implicates RNA Processing in the Pathogenesis of Neurodegenerative Disease", J. Neurosci., 1999, 19(4):1-11	
	AC	Camete-Soler et al., "Stability Determinants Are Localized to the 3'- Untranslated Region and 3'-Coding Region of the Neurofilament Light Subunit mRNA Using a Tetracycline-inducible Promoter", J. Biol. Chem., 1998, 273:12650-12654	
	AD	Cañete-Soler et al., "Characterization of Ribonucleoprotein Complexes and Their Binding Sites on the Neurofilament Light Subunit mRNA", J. Biol. Chem., 1998, 273:12655-12661	
	AE	Canete-Soler et al., "Mutation in Neurofilament Transgene Implicates RNA Processing in the Pathogenesis of Neurodegenerative Disease", J. Neurosci., 1999, 19:1273-1283	
	AF	Canete-Soler and Schlaepfer, Division of Neuropathology, University of Fennsylvania, "Similar poly(c)-sensitive RNA-binding complexes regulate the stability of the heavy and light neurofilament mRNAs 1-30	
	AG	Carden et al., "Two-Stage Expression of Neurofilament Polypeptides During Rat Neurogenesis with Early Establishment of Adult Phosphorylation Patterns", J. Neurosci., 1987, 7:3489-3504	
	АН	Chomczynski, P. and Sacchi, N., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction", Anal. Biochem., 1987, 162:156-159	
	AI	Collard et al., "Defective axonal transport in a transgenic mouse model of amyotrophic lateral sclerosis", Nature, 1995,375:61-64	
EXAMINER		DATE CONSIDERED	

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## Form PTO-1449 Modified

List of Patents and Publications Cited by Applicant (Use several sheets if necessary)

U.S. Department of Commerce

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Docket No. PENN-0788	Serial 10/082,		JL.	REC
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OTHER DO	CUMEN	TS (Including Author, Title, Date, Pertinent Pages, Etc.)
	AJ •	Cote et al., "Progressive Neuronopathy in Transgenic Mice Expressing the Human Neurofilament Heavy Gene: A Mouse Model of Amyotrophic Lateral Sclerosis", Cell, 1993, 73:35-46
	AK	Couillard-Despres et al., "Protective effect of neurofilament heavy gene overexpression in motor neuron disease induced by mutant superoxide dismutase", Proc. Nat'l Acad. Sci. USA, 1998, 95:9629-9630
	AL	Elder et al., "Absence of the Mid-sized Neurofilament Subunit Decreases Axonal Calibers, Levels of Light Neurofilament (FL-L), and Neurofilament Content", J. Cell Biol., 1998, 141:727-739
	AM	Eyer et al., "Pathogenesis of two axonopathies does not require axonal neurofilaments', Nature, 1998, 391:584-587
	AN	Eyer, J. and Peterson, A.C., "Neurofilament-Deficient Axons and Perikaryal Aggregates in Viable Transgenic Mice Expressing a Neurofilament-β-Galactosidase Fusion Protein", Neuron, 1994, 12:389-405
	AO	Fisher, C.L. and Pei, G.K., "Modification of a PCR-Based Site-Directed Mutagenesis Method", BioTechniques, 1997, 23:570-574
	AP	Gill et al., "Assembly Properties of Dominant and Recessive Mutations in the Small Mouse Neurofilament (NF-L) Subunit", J. Cell Biol., 1990, 111:2005-2019
	AQ	Karaosmanoglu et al., "Regional Differences in the Number of Neurons in the Myenteric Plexus of the Guinea Pig Small Intestine and Colon: An Evaluation of Markers Used to Count Neurons", Anat. Rec., 1996, 244:470-480
	AR	Lee et al., "Monoclonal Antibodies Distinguish Several Differentially Phosphorylated States of the Two Largest Rat Neurofilament Subunits (NF-H and NF-M) and Demonstrate Their Existence in the Normal Nervous System of Adult Rats", J. Neurosci., 1987, 7:3473-3488
EXAMINER		DATE CONSIDERED



## Form PTO-1449 Modified

List of Patents and Publications Cited by Applicant (Use several sheets if necessary)

U.S. Department of Commerce

EXAMINER

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Docket No. PENN-0788	Serial 10/082		IAP	THE COLUMN
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Filing Date February 21, 2001	Group <b>1632</b>	100/290	002	8

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OTHER DOCU	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AS	Lee et al., "A Mutant Neurofilament Subunit Causes Massive, Selective Motor Neuron Death: Implications for the Pathogenesis of Human Motor Neuron Disease", Neuron, 1994, 13:975-988		
	AT	Schwartz et al., "Axonal Dependency of the Postnatal Upregulation in Neurofilament Expression", J. Neurosci. Res., 1990, 27:193-201		
	AU	Schlaepfer, W.W. and Bruce, J., Simultaneous U-Regulation of Neurofilament Proteins During the Postnatal development of the Rat Nervous System", J. Neurosci. Res., 1990, 25:39-49		
	AV	Schwartz et al., "Actinomycin Prevents the Destabilization of Neurofilament mRNA in Primary Sensory Neurons", J. Biol. Chem. 1992, 267:24596-24600		
	AW	Schwartz et al., "Stabilization of neurofilament transcripts during postnatal development", Mol. Brain Res., 1994, 27:215-220		
	AX	Williamson et al., "Absence of neurofilaments reduces the selective vulnerability of motor neurons and slows disease caused by a familial amyotrophic lateral sclerosis-linked superoxide dismutase 1 mutant", Proc. Nat'l Acad. Sci USA, 1998, 95:9631-9636		
	AY	Wong et al., "Increasing Neurofilament Subunit NF-M Expression Reduces Axonal NF-H, Inhibits Radial Growth, and Results in Neurofilamentous Accumulation in Motor Neurons", J. Cell Biol., 1995, 130:1413-1422		
	AZ	Yamasaki et al., "Defective Expression of Neurofilament Protein Subunits in Hereditary Hypotrophic Axonopathy of Quail", Lab. Invest., 1992, 66:734-743		
	BA	Xu et al., "Increased Expression of Neurofilament Subunit NF-L Produces Morphological Alterations That Resemble the Pathology of Human Motor Neuron Disease", Cell, 1993, 73:23-33		

DATE CONSIDERED



EXAMINER

Sheet 04 of 04

## Docket No. Serial No. Form PTO-1449 Modified PENN-0788 10/082.032 List of Patents and Publications Applicant Cited by Applicant Schlaepfer et al. (Use several sheets if necessary) Filing Date Group U.S. Department of Commerce February 21, 2001 1632 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) BB Zhu et al., "Delayed Mutation of Regenerating Myelinated Axons in Mice Lacking Neurofilaments", Exp. Neurol., 1997. 148:299-316 Collard et al., "Defective axonal transport in a transgenic mouse model of amyotrophic lateral sclerosis", Nature 1995 375:61-64 Côté et al., "Progressive Neuronopathy in Transgenic Mice BD Expressing the Human Neurofilament Heavy Gene: A Mouse Model of Amyotrophic Lateral Sclerosis", Cell 1993 73:35-46 BE Gill et al., "Assembly Properties of Dominant and Recessive Mutations in the Small Mouse Neurofilament (NF-L) Subunit", J. Cell Biol. 1990 111:2005-2019

DATE CONSIDERED